

**REMARKS**

Applicant expresses gratitude to the examiner for withdrawing the rejection of claim 44 under 35 U.S.C. § 112, first paragraph.

By this amendment, claims 28 and 44-46 have been amended and claim 48 has been added. Independent claims 28 and 45 have been amended by incorporating the subject matter of claim 46. No new matter has been added.

**Response to Rejections under 35 U.S.C. § 103**

Claims 28, 30, 32, 34, 37, 39, 41, 42, and 45 were rejected under 35 U.S.C. § 103(a) as being obvious over Kasahara (U.S. 3,971,848) in view of Van Leuven (U.S. 4,267,168) as evidenced by Muller (U.S. 5,624,903) and Bringloe (U.S. 4,765,478). The Examiner provides counterarguments on pages 12-13 of the Office Action. Without acquiescing to the propriety of these assertions, and only in the interest of advancing prosecution, Applicant submits that independent claim 28 has been amended to incorporate the subject matter of claim 46, which was not rejected based on the above-cited combination of references. Accordingly, Applicants submit that this rejection has been rendered moot.

To the extent that the rejection of claim 46 based on the combination of Van Leuven in view of JP '256, as evidenced by Muller and Yunis (U.S. 5,877,209) applies to amended independent claim 28, independent claim 45, or claims depending therefrom, Applicants respectfully disagree and traverse.

Claim 46 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Van Leuven in view of JP '256, as evidenced by Muller and Yunis (U.S. 5,877,209). The Examiner asserts that Van Leuven discloses compositions which act as lubricants to be

used during delivery at the time of birth containing water, propylene glycol, and glycerine. The Examiner asserts that Muller discloses that glycerol is an isotonicizing substance and that Yunis discloses that propylene glycol and glycerine are humectants. The Examiner acknowledges that Van Leuven does not disclose polyacrylic acid, but asserts that JP '256 discloses a lubricant consisting essentially of polyacrylate for animal birthing. The Examiner asserts that it would have been obvious to combine these references to arrive at the claimed composition for use as a lubricant during birthing. With regard to the limitations of reducing injuries to the mother's birth canal, the risk of episiotomy, the risk of vaginal interventions, and the risk of cesarean sections during birthing, the Examiner asserts that Van Leuven discloses that the composition can be used to aid in delivery of a baby at birth by being applied to vaginal tissue of the baby's mother and therefore one skilled in the art would expect such aid would result in reduced injuries and/or interventions during birthing, absent evidence to the contrary.

Applicants respectfully submit that Van Leuven is silent as to a method for reducing the frictional force between an item to be delivered and a mother's birth canal, as a result of which injuries to the mother's birth canal, the risk of episiotomy, the risk of vaginal interventions, and the risk of caesarian sections during vaginal child birthing can be reduced. Furthermore, vaginal child birthing can be facilitated by quite different means. In particular, the expression "applied to vaginal tissue of the baby's mother" as used in column 6, lines 53-55 of Van Leuven does not necessarily mean that the composition is introduced into the mother's birth canal to cover the birth canal surface, but more likely refers to applying the composition externally. Moreover, the expression also encompasses a perineal massage, which is clearly distinguished from the claimed method of lubricating the birth canal as pointed out by the Examiner on page 12 of the

subject Office Action. Thus, there is no evidence of record that Van Leuven actually suggests the claimed method of reducing the frictional force between an item to be delivered and a mother's birth canal, as a result of which injuries to the mother's birth canal, the risk of episiotomy, the risk of vaginal interventions, and the risk of caesarian sections during vaginal child birthing can be reduced.

Applicants submit that Van Leuven discloses that it is important to maintain the composition in liquid form and to not allow it to gel. See col. 6, lines 9-24. Therefore, Van Leuven teaches away from using non-liquid compositions. Similarly, JP '256 discloses an aqueous solution. Thus, the cited combination does not suggest that the composition be in the form of a paste, gel, cream, suppository, or foam as recited in independent claim 28. Favorable reconsideration and withdrawal of the rejection of claim 46 as it applies to amended independent claims 28 and 45 are respectfully requested for at least these reasons.

Further, the composition of Van Leuven contains inorganic molecules and is therefore not an organic composition as is recited in claims 28 and 45. Favorable reconsideration and withdrawal of the rejection of claim 46 as it applies to amended independent claim 28 are respectfully requested for this additional reason.

Applicants submit that the simple mention in Van Leuven that the composition can be used to aid in delivery of a baby would not have suggested a method of reducing the frictional force between an item to be delivered and a birth canal surface of a mother in human vaginal child birthing so as to reduce injuries to the mother's birth canal, the risk of episiotomy, the risk of vaginal interventions, and the risk of cesarean sections during birthing, with a reasonable expectation of success. Favorable reconsideration

and withdrawal of the rejection of claim 46 as it applies to amended independent claims 28 and 45 are respectfully requested for this additional reason.

Also, none of the cited references disclose **an effective amount** of the organic lubricant composition to cover said birth canal surface with the onset of labor or the step of additionally applying an amount of said composition to said birth canal surface during labor wherein said **additional amount is effective in keeping the birth canal surface covered** with said lubricant composition so that a lubricant layer is formed between said birth canal surface and said item to be delivered until said item is delivered. Thus, the cited combination does not suggest the invention “as a whole” as is required by 35 U.S.C. § 103(a). Favorable reconsideration and withdrawal of the rejection of claim 46 as it applies to amended independent claims 28 and 45, and claims depending therefrom, are respectfully requested for this additional reason.

Claim 29 was rejected under 35 U.S.C. § 103(a) as being obvious over Kasahara (U.S. 3,971,848) in view of Van Leuven (U.S. 4,267,168) as evidenced by Muller and Bringloe and further in view of JP 46-24256 (“JP ‘256”). The Examiner maintains that the combination of cited references and the general knowledge discloses that the method is effective in humans and the step of applying additional amounts and that JP ‘256 is only cited for the amount of polyacrylic acid. Applicants respectfully disagree and traverse the rejection for at least the above reasons. Claim 29 depends from claim 28, which has been amended to exclude a feature that is essential for Kasahara. Accordingly, the rejection has been rendered moot. Further, Applicants submit that none of the cited references disclose **an effective amount** of the organic lubricant composition to cover said birth canal surface with the onset of labor or the step of

additionally applying an amount of said composition to said birth canal surface during labor wherein said **additional amount is effective in keeping the birth canal surface covered** with said lubricant composition so that a lubricant layer is formed between said birth canal surface and said item to be delivered until said item is delivered. Even further, the cited combination does not disclose or suggest the claimed method using polyacrylic acid in a concentration of from 0.25 to 5% by weight. Thus, the cited combination does not suggest the invention “as a whole” as is required by 35 U.S.C. § 103(a). Favorable reconsideration and withdrawal of the rejection of claim 29 are respectfully requested for this additional reason.

Claim 31 was rejected under 35 U.S.C. § 103(a) as being obvious over Kasahara (U.S. 3,971,848) in view of Van Leuven (U.S. 4,267,168) as evidenced by Muller and Bringloe and further in view of Behl et al. (U.S. 5,580,574). The Examiner asserts that Behl teaches that the purpose of CMC in its compositions is to obtain the desired consistency of the gel, not to facilitate or enhance transdermal penetration. Applicants respectfully disagree and traverse the rejection for at least the above reasons. Claim 31 depends from claim 28, which has been amended to exclude a feature that is essential for Kasahara. Accordingly, the rejection has been rendered moot. Further, Applicants submit that none of the cited references disclose **an effective amount** of the organic lubricant composition to cover said birth canal surface with the onset of labor or the step of additionally applying an amount of said composition to said birth canal surface during labor wherein said **additional amount is effective in keeping the birth canal surface covered** with said lubricant composition so that a lubricant layer is formed between said birth canal surface and said item to be delivered until said item is delivered. Even

further, the cited combination does not disclose or suggest the claimed method further comprising a thickener. Thus, the cited combination does not suggest the invention “as a whole” as is required by 35 U.S.C. § 103(a). Favorable reconsideration and withdrawal of the rejection of claim 31 are respectfully requested for this additional reason.

Claim 33 was rejected under 35 U.S.C. § 103(a) as being obvious over Kasahara (U.S. 3,971,848) in view of Van Leuven (U.S. 4,267,168) as evidenced by Muller and Bringloe and further in view of Roder et al. (U.S. 6,217,885). The Examiner asserts that no new arguments were provided, thus these claims remain obvious because of the maintained rejection of independent claim 28. Applicants respectfully traverse the rejection for at least the above reasons. Claim 33 depends from claim 28, which has been amended to exclude a feature that is essential for Kasahara. Accordingly, the rejection has been rendered moot. Further, Applicants submit that none of the cited references disclose **an effective amount** of the organic lubricant composition to cover said birth canal surface with the onset of labor or the step of additionally applying an amount of said composition to said birth canal surface during labor wherein said **additional amount is effective in keeping the birth canal surface covered** with said lubricant composition so that a lubricant layer is formed between said birth canal surface and said item to be delivered until said item is delivered. Even further, the cited combination does not disclose or suggest the claimed method comprising carob flours in a concentration of from 0.5 to 3% by weight. Thus, the cited combination does not suggest the invention “as a whole” as is required by 35 U.S.C. § 103(a). Favorable

reconsideration and withdrawal of the rejection of claim 29 are respectfully requested for this additional reason.

Claims 35-36 were rejected under 35 U.S.C. § 103(a) as being obvious over Kasahara (U.S. 3,971,848) in view of Van Leuven (U.S. 4,267,168) as evidenced by Muller and Bringloe and further in view of Kasahara '797 (U.S. Patent 3,814,797). The Examiner asserts that no new arguments were provided, thus these claims remain obvious because of the maintained rejection of independent claim 28. Applicants respectfully traverse the rejection for at least the above reasons. Claims 35-36 depends from claim 28, which has been amended to exclude a feature that is essential for Kasahara. Accordingly, the rejection has been rendered moot. Further, Applicants submit that none of the cited references disclose **an effective amount** of the organic lubricant composition to cover said birth canal surface with the onset of labor or the step of additionally applying an amount of said composition to said birth canal surface during labor wherein said **additional amount is effective in keeping the birth canal surface covered** with said lubricant composition so that a lubricant layer is formed between said birth canal surface and said item to be delivered until said item is delivered. Even further, the cited combination does not disclose or suggest the claimed method further comprising the claimed amounts of the composition being applied to cover the birth canal. Thus, the cited combination does not suggest the invention "as a whole" as is required by 35 U.S.C. § 103(a). Favorable reconsideration and withdrawal of the rejection of claims 35-36 are respectfully requested for this additional reason.

Claim 43 was rejected under 35 U.S.C. § 103(a) as being obvious over Kasahara (U.S. 3,971,848) in view of Van Leuven (U.S. 4,267,168) as evidenced by Muller and Bringloe and further in view of Dettmar (U.S. Patent 4,652,446). The Examiner asserts that no new arguments were provided, thus these claims remain obvious because of the maintained rejection of independent claim 28. Applicants respectfully traverse the rejection for at least the above reasons. Claim 43 depends from claim 28, which has been amended to exclude a feature that is essential for Kasahara. Accordingly, the rejection has been rendered moot. Further, Applicants submit that none of the cited references disclose **an effective amount** of the organic lubricant composition to cover said birth canal surface with the onset of labor or the step of additionally applying an amount of said composition to said birth canal surface during labor wherein said **additional amount is effective in keeping the birth canal surface covered** with said lubricant composition so that a lubricant layer is formed between said birth canal surface and said item to be delivered until said item is delivered. Even further, the cited combination does not disclose or suggest the claimed method comprising crosslinked polyacrylic acid. Thus, the cited combination does not suggest the invention “as a whole” as is required by 35 U.S.C. § 103(a). Favorable reconsideration and withdrawal of the rejection of claim 43 are respectfully requested for this additional reason.

Independent claim 44 was rejected under 35 U.S.C. § 103(a) as being obvious over Van Leuven (U.S. 4,267,168) in view of JP 46-24256 (JP ‘256). The Examiner was not convinced by the amendments and arguments that Van Leuven discloses a list of ingredients that are excluded by the phrase “consisting of” and discloses that sulfonic acid is essential to the lubricity and viscosity of the composition. The Examiner asserts



that claim 44 now recites “surface-active substances” at line 17, which would include dodecyl benzene sulfonic acid. Applicants submit that claim 44 has been amended by deleting “surface-active substances.” Accordingly, Applicants respectfully submit that independent claim 44 now excludes dodecyl benzene sulfonic acid, which is required by Kasahara. Favorable reconsideration and withdrawal of the rejection of claim 44 are respectfully requested for this additional reason.

Claim 46 has been amended by being recast in independent form and by excluding surface-active substances from the lubricant organic substance. The specification discloses surface active substances in the paragraph bridging pages 6 and 7 and page 9, 1<sup>st</sup> paragraph. Accordingly, the claim amendments do not present any issues of new matter because Applicant is only claiming, in these claims, less than Applicant has a right to claim. See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) (“[the] specification, having described the whole, necessarily described the part remaining.”); see also M.P.E.P. § 2173.05(i) citing *In re Johnson* (“If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims.”). Because a surface-active substance, i.e., dodecyl benzene sulfonic acid, is essential to the composition of Van Leuven, Applicant submits that claim 46 is distinguished over the combination of cited references for at least this additional reason.

**New Claim**

Claim 48 has been added based on pending claim 45, but specifically directed to a method of reducing the risk of cesarean sections during human vaginal child birthing. According to the method of claim 48, the composition is in the form of a paste, gel, cream, suppository, or foam, and has lubricant film-forming properties that effect reduced risk of cesarean sections during birthing. Because none of the cited references teach or suggest that the risk of cesarean sections can be reduced by injecting a lubricant into a mother's vagina, Applicants submit that claim 48 is not rendered obvious by the cited references. Furthermore, evidence for the unexpected results obtained by using the claimed method was presented in Applicant's August 12, 2011, response. Specifically, in the Scientific Expert Report on page 7, clinical studies in human mothers demonstrated that using the claimed method reduced cesarean sections by 19% compared to the control group. Accordingly, Applicants respectfully submit that new claim 48 is also patentable over the citations of record.

Conclusion

In view of the foregoing, it is submitted that the present application is now in condition for allowance. Reconsideration and allowance of the pending claims are requested. The Director is authorized to charge any fees or credit any overpayment to Deposit Account No. 02-2135.

A Notice of Allowance is respectfully requested.

The Examiner is invited to telephone the undersigned if it is deemed to expedite allowance of the application.

Respectfully submitted,

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